

U.S. Patent Application No. 09/627,580
Amendment dated July 14, 2003
Reply to Office Action dated April 9, 2003

REMARKS

Favorable reconsideration and continued examination of this application is respectfully requested.

Claim 1, claims 41-58, and newly added claims 59-64 are currently pending in the present application.

Claim 49 has been amended to correct a typographical error.

Support for newly added claims 59-61 can be found, for example, at page 26, line 27 to page 27, line 5 and at page 53, lines 15-16 of the specification. Support for newly added claims 62-64 can be found, for example, in original claim 1, at page 26, line 27 to page 27, line 5, and at page 53, lines 15-16 of the specification. No new matter has been added. Entry of the new claims is respectfully requested.

Applicants wish to thank the Examiner, and her Primary Examiner, for the courtesies extended to Applicants' undersigned representative during the telephone interview of June 30, 2003. During the telephone interview, the Examiners indicated that a reassessment by the Examiners would be made of the rejections set forth in the present Office Action in view of the prosecution history of U.S. Patent No. 6,126,899 to Woudenburg et al., the grandparent application of the present application. Copies of the Declaration of Federico M. Goodsaid under 37 CFR 1.132 and of the Declaration of Kenneth J. Livak under 37 CFR 1.132, both filed originally on March 8, 2000 in connection with U.S. Patent Application No. 08/831,983, the application that matured into of U.S. Patent No. 6,126,899 ("the '899 patent"), are concurrently filed with this amendment. The Declarations (copies enclosed) are by experts in the field of technology. Both experts state in their respective Declarations that experiments

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with the claimed invention showed surprising and unexpected results. In particular, the Declaration of Frederico M. Goodsaid states at pages 2 and 3 many of the differences between the claimed invention and the very same prior art references used in the Office Action of April 9, 2003 for the present application. Furthermore, the Declaration of Kenneth J. Livak states at pages 2-4 many of the differences between the claimed invention and the very same prior art references used in the Office Action of April 9, 2003 for the present application. Moreover, the Declarations state why these experts consider the invention then-claimed and presently claimed to be nonobvious in view of the prior art. To the extent the Declarations are applicable to the claims of the '899 patent, these Declarations are likewise applicable to and are in support of the present claims.

Applicants also wish to thank Examiner Shahnan-Shah for the phone call of July 8, 2003, and the indication that the attached Declarations would be considered by the Examiners in connection with the present application.

Applicants gratefully acknowledge the Examiner's withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, made in paragraph 9 in the Office Action mailed May 31, 2002 (Paper No. 9), and the rejection of claim 1 under 35 U.S.C. § 102(b) made in paragraph 10 in the Office Action mailed May 2, 2001 (Paper No. 5).

In the present Office Action, claims 1 and 41-58 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,038,151 to Fadler et al. ("Fadler et al."), further in view of U.S. Patent No. 5,612,473 to Wu et al. ("Wu et al."), and U.S. Patent No. 5,585,242 to Bouma et al. ("Bouma et al. '242") and U.S. Patent No. 5,645,801 to Bouma et al. ("Bouma et al. '801"), or U.S.

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Patent No. 5,639,612 to Mitsuhashi et al. ("Mitsuhashi et al."). Applicants request reconsideration and allowance of the pending claims for at least the following reasons.

The Office Action asserts that the Fadler et al. device comprises a substrate with a sample distribution network, one or more detection chambers, supply ports, channels, and viewing wells.

The Office Action also asserts that "Each of the wells is connected to a predetermined liquid specimen supply port by the means of channels, which provide dead-end fluid connection." Fadler et al. describes that located adjacent to each viewing well 14 are a pair of overflow chambers 17, 18, that open out of two major surfaces 14, 15 of the viewing well 14. Each overflow chamber 17, 18 is connected to its respective viewing well 14 by connecting passageways 20, 22. The overflow chambers 17, 18 assist in the complete filling of the viewing well 14 and in the elimination of bubbles therefrom (*see*, Fig. 1; col. 3, lines 23-34) of Fadler et al. The overflow chambers 17, 18 are important to the correct operation of the viewing well 14 (*see*, col. 4, lines 50-59). Accordingly it is submitted that Fadler et al. does not provide the dead-end fluid connection of the presently claimed invention.

The Office Action concedes that the device of Fadler et al. is used for detecting or quantitating the desired type or types of microorganisms in a liquid sample. The Office Action asserts that the phrase "the desired type or types of microorganisms" as described in Fadler et al. encompasses the phrase "plurality of different analytes" of the present invention. This encompassment can only occur with impermissive hindsight. The Office Action further concedes Fadler et al. does not teach a device for detecting or quantitating specifically a plurality of different polynucleotide sequences in a liquid sample. *See* page 4 of the Office Action.

The Office Action also concedes that Fadler et al. fails to teach a device for detecting or quantitating specifically a plurality of polynucleotide sequences, the use of oligonucleotide primers with or without fluorescent labels, and of polymerase chain reaction or ligase chain reaction (*see* page 4). There is no motivation or teaching provided in the prior art whereby the device of Fadler et al. would be thought to be used with oligonucleotide primers with or without fluorescent labels, and that the device of Fadler et al. is utilized for polymerase chain reactions or ligase chain reactions.

The Office Action asserts that Fadler et al. teaches that many changes, alterations, modifications and other uses of the application of the subject device will become apparent to those skilled in the art. Fadler et al. relates to a device for detection of selected microorganisms using wells containing selected cultured media components. There is no teaching or suggestion in this reference to modify the device of Fadler et al. to detect specific polynucleotides in a sample. Rather, Fadler et al. is only concerned only with the detection of micro-bioorganisms using viability-selected media.

Accordingly, it is respectfully submitted that Fadler et al. fails to disclose a device for detecting or quantitating the plurality of different analytes in a liquid sample. Fadler et al. fails to disclose or suggest channel means providing a dead-end fluid connection between each of said chambers and said inlet, and teaches away from such an embodiment. In fact, a dead-end fluid connection would render the device of Fadler et al. unusable. Fadler et al. is only concerned with microorganisms in a liquid sample. Contrary to the position taken in the Office Action, there is no motivation for a person of ordinary skill in the art to combine the teachings of Fadler et al. with Wu et al., and Bouma et al. '242, and Bouma et al. '801, or Mitsuhashi et al. Such motivation would be required to render independent claim 1 unpatentable but simply does not exist. Moreover, the Applicants submit that the passage of

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nearly 20 years since the filing date of Fadler et al. July 29, 1976 is further evidence that the skilled person in the art would not have turned to Fadler et al. at the time of the claimed invention to prepare a device for polynucleotide detection in accordance with the claimed invention.

Wu et al. mentions microtiter plates (*see*, col. 24, lines 4-7) and microfuge tubes for use in a Perkin Elmer 9600 thermocycler (*see*, col. 24, lines 32-34) as devices for nucleic acid hybridization or PCR amplification. The device of present claim 1 is neither taught nor suggested. Wu et al. also provides no motivation for how devices for nucleic acid hybridization or PCR amplification should be improved.

Similarly, Mitsuhashi et al. mentions only standard microtiter plates (*see*, col. 18, lines 30-35) as a device for nucleic acid hybridization or PCR amplification. The device of present claim 1 is neither taught or suggested. Mitsuhashi et al. provides no motivation for how devices for nucleic acid hybridization or PCR amplification should be improved.

Bouma et al. '242 relates to a particular detection technique relating to total internal reflection, for use with a single reaction vessel, as is evident from Figs. 1-2.

Bouma et al. '801 describes a device wherein a sample is loaded into a reaction chamber of the device which is then sealably matched with a detection chamber to form a sealed reaction/detection unit. Among other things, Bouma et al. '801 does not provide for a dead-end fluid connection between each chamber and an inlet.

Neither Wu et al., Bouma et al. '242, Bouma et al '801, Mitsuhashi et al. nor any combination thereof overcomes the deficiencies of Fadler et al. There is no motivation to combine Fadler et al. with Wu et al., Bouma et al. '242, and Bouma et al '801, or Mitsuhashi et al., particularly in the multi-way

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combination cited in the Office Action. Even if these references were combined, which Applicants contend is impermissible, the device for detecting or quantitating one or more of a plurality of different polynucleotide sequences in a liquid sample, according to present claim 1, would not result. One of ordinary skill would not look to Wu et al., Bouma et al. '242, Bouma et al. '801, Mitsuhashi et al., nor any combination thereof, to modify Fadler et al.

In view of the foregoing, it is respectfully submitted that independent claim 1 and claims 41-48 depending therefrom, are patentably distinguishable over the cited references and the proposed combinations thereof. Favorable reconsideration and withdrawal of the rejection is respectfully requested.

Applicants would like to reiterate what Applicants' representative stated during the telephone interview of June 30, 2003, that is, that independent claim 1 of the present application includes all the limitations to independent claim 1 of the allowed and patented '899 patent. The face of the '899 patent lists Fadler et al., Wu et al., Bouma et al. '242, and Mitsuhashi et al. as prior cited art. Applicants contend that full faith and credit should be given to the search and action of a previous examiner (*See* M.P.E.P. § 706.04), and claims 1 and 41-58 of the present application should accordingly be allowed.

Newly added claims 59-61 depend from independent claim 1, are patentably distinguishable over the cited references and combinations thereof for the reasons set forth above in relation to independent claim 1, and in addition in consideration of the additional features recited in new claims 59-61. New independent claim 62 and dependent claims 63 and 64 are also deemed patentably distinguishable over the cited references and combinations thereof for the reasons set forth above in

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relation to independent claim 1, and in consideration of the additional features recited in new claims 62-64.

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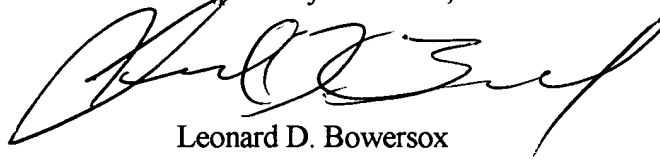
CONCLUSION

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration of the present application and a timely allowance of the pending claims.

Should the Examiner deem that any further action by the Applicants or Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

If there are any fees due in connection with the filing of this response, please charge the fees to deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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Enclosures:

Copy of Declaration of Federico M. Goodsaid originally filed March 8, 2000
in U.S. Patent Application No. 08/831,983
Copy of Declaration of Kenneth J. Livak originally filed March 8, 2000
in U.S. Patent Application No. 08/831,983
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